

# Supplemental Notice of Allowability

Application No.

10/614,233

Examiner

Raymond J. Henley III

Applicant(s)

EBDRUP ET AL.

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS ~~IS~~ (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is ~~responsive~~ <sup>Supplemental</sup> to the Notice of Allowability of May 20, 2005.
2. ☒ The allowed claim(s) is/are 1-4, 7-26, 29, 31, 32 and 35-66.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All b) ☐ Some\* c) ☐ None of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

~~Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.~~  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413B)  
Paper No./Mail Date 071420051.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

**RAYMOND HENLEY III  
PRIMARY EXAMINER**

*461014*

### **EXAMINER'S AMENDMENT**

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Rosemarie R. Wilk-Orescan on July 14, 2005.

As a result of the following amendment, the claims which stand allowed in the present application are claims 1-4, 7-26, 29, 31, 32 and 35-66.

The application has been amended as follows:

#### In the Claims:

In claim 1, "a) inhibiting the lipolytic activity of hormone sensitive lipase against ...as well as citrate or malonyl-CoA; and/or" (lines 2-8) has been deleted;

In claim 1, at lines 9, 11 and 12, "d)", "e)" and "f)" have been deleted;

Claims 27 and 28 have been canceled;

In claim 29, line 1, "27" has been changed to ---1---, and line 3, "obesity," has been deleted; and

Claims 30, 33 and 34 have been canceled.

#### *Examiner's Comments*

The above amendments have been made to avoid any potential issues under 35 U.S.C. § 102/103 over the disclosure of U.S. Patent 6,267,952 (Mandeville, et al.), a newly discovered reference.

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Mandeville et al. teach methods for treating obesity in a patient by administering a patient an effective amount of a polymer that has been substituted with one or more groups that inhibit lipases, which are enzymes that are responsible for the hydrolysis of fat (see the abstract). One such compound taught by the patentees is represented in claims 1-5 of the patent:

<p>What is claimed is:</p> <p>1. A method for treating obesity in a mammal, comprising the step of orally administering to the mammal an effective amount of a polymer substituted with at least one group having the following structure:</p>	<p>wherein,</p> <p><math>R^1</math> is a hydrophobic moiety, a substituted or unsubstituted aliphatic group or a substituted or unsubstituted aromatic group;</p> <p><math>Z</math> is an oxygen, alkylene, sulfur, <math>-\text{SO}_2-</math>, <math>-\text{CO}_2-</math>, <math>-\text{NR}^2-</math>, <math>-\text{CONR}^2-</math>, <math>-\text{PO}_3\text{H}-</math> or a spacer group; and</p> <p><math>R^2</math> is a hydrogen, an unsubstituted or substituted aliphatic group or unsubstituted or substituted aromatic group.</p> <p>2. The method of claim 1, wherein the polymer is a polyacrylamide, a polyvinyl alcohol, a polyether or a polyallyl amine.</p> <p>3. The method of claim 2, wherein the polymer is a copolymer.</p> <p>4. The method of claim 1, wherein the polymer is a fat-binding polymer.</p> <p>5. The method of claim 1, wherein the polymer is co-administered with a fat-binding polymer.</p>
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(compare the structure that set forth in present claim 1, where  $R^1$  and  $R^2$  may be hydrogen and  $R^3$  may be various aliphatic or aromatic groups, which may be substituted by various substituents, such as "oxo").

The claims as amended would not be anticipated by the teachings of Mandeville et al. because the only patient taught for treatment by the patentees is an obese patient, (e.g., see col. 1, lines 48-63 and col. 9, lines 46-56) while the present claims are directed to i) increasing insulin sensitivity in adipose tissue, skeletal muscle, liver or pancreatic  $\beta$  cells; and/or ii) modulating insulin secretion from pancreatic  $\beta$  cells; and/or iii) inhibiting male fertility ... [by] administering

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to a patient in need of such method ... . Therefore, the patient populations of the claimed methods are either diabetic patients, e.g., in need of increased insulin sensitivity or modulated insulin secretion, or male patients in need of inhibited fertility. Neither of these patients are necessarily taught by the patentee and thus the claims are not anticipated by the patent.

Also, while it may be proposed that *some* diabetic patients are obese and it may have been “obvious” to administer the boron compounds of Mandeville et al. to such patients for the purpose of treating obesity or inhibiting lipase, such would not support a conclusion of obviousness given that the present claims require the objectives of i) increasing insulin sensitivity in adipose tissue, skeletal muscle, liver or pancreatic  $\beta$  cells; and/or ii) modulating insulin secretion from pancreatic  $\beta$  cells, which could not be inherent in the “obvious” diabetic host.

In particular, it has been held that inherency *must* be a necessary result and not merely a possible result. *In re Oelrich* (CCPA 1981) 212 USPQ 323. Here, if the Examiner were to conclude that the use of the claimed actives in a host not specifically taught by the reference “would have been obvious”, such a conclusion would be, in essence, creating a *possible* host and thus not a host that *necessarily* exists in the reference. If the host does not necessarily exist, logic dictates that any physiological function or drug effect that would be present in such a host would also be only a possible function or effect and most certainly not a function or effect that would be necessarily present.

The Examiner is guided in his opinion by MPEP § 2112(IV) “The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955,

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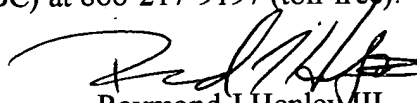
1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art)”(emphasis added).

Accordingly, claims 1-4, 7-26, 29, 31, 32 and 35-66 stand allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Raymond J Henley III  
Primary Examiner  
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July 14, 2005